



Australian Government

Department of Health
Therapeutic Goods Administration

Advisory Committee on Medicines

Meeting Statement

Out of Session Meeting, Tuesday 26 April 2022

Section A: Pre-market registration applications referred for advice

At this meeting, the committee's advice was sought on 2 applications under evaluation by the TGA. The applications included:

Active ingredient (TRADENAME)	Sponsor	Therapeutic area
Type C (extension of indications)		
remdesivir (VEKLURY)	Gilead Sciences Pty Ltd	For treatment of COVID-19

*These application types are published on the Prescription medicines: applications under evaluation page <https://www.tga.gov.au/prescription-medicines-applications-under-evaluation>

In addition to:

- One seeking a major variation (change in dosage)

Further details of the ACM discussion and advice associated with these items may be released within the Australian Public Assessment Reports (AusPARs). Please note that there is a delay from when an application was considered at ACM and the publication of the AusPAR. To browse all AusPARs see: <<https://www.tga.gov.au/browse-auspars-active-ingredient>>

Further information

For further information on the Advisory Committee on Medicines, please visit:

<https://www.tga.gov.au/committee/advisory-committee-medicines-acm> or contact the ACM Secretary by email: ACM@health.gov.au.